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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,385	09/26/2003	Isaac Shemer	IMP031-228863	8534

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EXAMINER

MULLEN, KRISTEN DROESCH

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/672,385

Applicant(s)

SHEMER ET AL.

Examiner

Kristen Mullen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/15/05 (change of address).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12, 14-26, 28 and 30-32 is/are rejected.
- 7) ☒ Claim(s) 11, 13, 27 and 29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/29/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION.

Information Disclosure Statement

1. The examiner is unable to locate the copy of JP 436 5493 provided with the filing of the IDS of the parent application. The examiner respectfully requests an additional copy of this reference. This reference has not been considered at this time.
2. References CH (Bers), CI (Zipes) and CJ (Josephson) listed on the IDS appear to be books. Applicants have provided only the cover-pages for each reference. These references have been considered only to the extent of what was provided by applicants.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-8, 12, 16-24, 28 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Cohen (5,267,560).

Regarding claims 1-8, Cohen shows a method of applying a signal to a site on the right ventricular septum of the heart and configuring the signal to be capable of modifying, increasing or decreasing the contractility of a portion of the heart, the left ventricle, the septum and the right ventricle of the heart (Col. 3, line 34-Col. 4, line 33; Col. 10, lines 16-63; Col. 12, lines 12-63; Col 13, lines 29-61; Col. 14, line 47- Col. 15, line 2). Configuring the signal to be capable of decreasing the contractility of the heart would include applying conventional pacing to the heart that increases the %systole compared to %systole of normal sinus rhythm.

With respect to claim 12, Cohen shows applying the signal comprises applying a series of pulses at a rate less than about 100Hz, due to the fact that rates for pacing the heart are less than 100 Hz.

Regarding claim 16, Cohen shows applying the signal to a site adjacent to an intersection of the septum and the right ventricular free wall (Figs. 8c, 9, 10c, 11)

With respect to claim 17, Cohen shows a set of one or more electrodes and a control unit adapted to drive the electrode set to apply a signal to the septum (Figs. 8c, 9, 10c, 11)

Regarding claims 18-24, Cohen shows the control unit is capable of configuring the signal to be capable of modifying, increasing or decreasing the contractility of a portion of the heart, the left ventricle, the septum and the right ventricle of the heart.

With respect to claim 28, Cohen shows the control unit is capable of driving the electrode set to apply a series of pulses at a rate less than about 100Hz, due to the fact that rates for pacing the heart are less than 100 Hz, typically in the range of 50-150 paces/minute.

Regarding claim 32, Cohen shows the control unit is adapted to drive the electrode set to apply the signal to a site adjacent to an intersection of the septum and the right ventricular free wall (Figs. 8c, 9, 10c, 11).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 9-10, 14-15, 25-26, and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen (5,267,560) as applied to claims 1 and 17 above and further in view of Herscovici (4,543,956). Cohen is as explained before. Cohen fails to show the specific waveform shapes of the pulses and the amplitude of the pulses. Attention is directed to Herscovici who shows that it is well known to apply square pulses and to provide the biphasic square pulses in order to provide rapid electrode charge neutralization and enhance subsequent capture detection (Abs. Fig. 1). Herscovici also teaches that it is critical to use pulses having very high amplitude greater than 8 mA and 10mA and a short duration in order to compensate for an increase in cathodal current threshold of biphasic waveforms (Col. 3, lines 13-45). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method and apparatus of Cohen to include applying square pulses since it is well known in the art to do so, to apply biphasic square pulses in order to provide rapid electrode charge neutralization and enhance subsequent capture detection and apply pulses greater than 8mA and 10mA in order to compensate for an increase in the cathodal current threshold of biphasic waveforms.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1, 2 and 5-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 4-5 and 18 (which include the limitations of claim 1) of U.S. Patent No. 6,330,476.

For double patenting to exist as between the rejected claims and the patent claims, it must be determined that the rejected claim is not patentably distinct from claims 2, 4-5 and 18. In order to make this determination, it first must be determined whether there are any differences between the rejected claims and claims and, if so, whether those differences render the claims patentably distinct.

The difference between claims 1, 2 and 5-7 of the application and claims 2, 4-5 and 18 of the patent lies in the fact that the patent claim includes many more elements and is thus much more specific. It is clear that all the elements of claims 1, 2 and 5-7 are to be found in claims 2, 4-5 and 18 (as it encompasses claim 1). Thus, the invention of claims 2, 4-5 and 18 of the patent is in effect a "species" of the "generic" invention of claims 1, 2 and 5-7 of the application. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29

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USPQ2d 2010 (Fed. Cir. 1993). Since claims 1, 2 and 5-7 are anticipated by claims 2, 4-5 and 18 of the patent, they are not patentably distinct from claims 2, 4-5 and 18.

Allowable Subject Matter

9. Claims 11, 13, 27 and 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



kdm

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